



BILLING CODE: 4140-01-P

DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**Government-Owned Inventions; Availability for Licensing**

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email [ncitechtransfer@mail.nih.gov](mailto:ncitechtransfer@mail.nih.gov). A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention: Biomarker signature development: microRNAs as biodosimetry markers

Description of Technology:

Alterations in microRNAs (miRNAs), a type of small non-coding RNAs, have been reported in cells/tumors subjected to radiation exposure, implying that miRNAs play an important role in cellular stress response to radiation.

Researchers at the National Cancer Institute evaluated small non-coding RNAs, long non-coding RNAs (lncRNA), and mRNA as potential non-invasive biomarkers for radiation biodosimetry. While the use of miRNAs as radiation biomarkers has been reported, the integrated use of miRNAs, mRNAs and lncRNAs to accurately determine radiation doses is novel and has not been published. The researchers characterized a unique method of examining miRNA levels along with levels of its target mRNA and lncRNA to determine radiation exposure using whole blood samples from mice exposed to 2, 4, 8, 12 and 15 Gy irradiation. In doing so, they discovered distinct miRNA, mRNA and lncRNA biomarker signatures that inform degree of radiation exposure.

Integrated analysis of miRNA, mRNAs, and lncRNAs to assess radiation exposure after mass-casualty incidents could provide a valuable tool in identifying biomarkers, and in the development and appropriate implementation of effective medical countermeasures. This application could potentially also be used to immediately detect, and therefore circumvent or mitigate non-specific injury from cancer radiotherapy treatments.

Potential Commercial Applications:

- Diagnostic for radiation exposure, including for therapeutic procedures

Value Proposition:

- Blood-based biomarker assay for circulating miRNAs
- Could be developed as part of point-of-care and high-throughput screening platforms
- Immediate medical care based on amount of radiation exposure is critical for giving appropriate care to affected individuals

Development Stage:

In-vivo testing

Inventor(s):

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Intellectual Property:

HHS Reference No. E-066-2015/0-US-01

US Provisional Application 62/244,044 (HHS Reference No. E-066-2016/0-US-01) filed October 20, 2015 entitled “Biomarker signature development: microRNAs as biodosimetry markers”

Collaboration Opportunity: Researchers at the NCI seek parties interested in licensing or co-development for microRNA biomarker signatures as biodosimetry markers.

Contact Information:

Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov or phone: 240276-5515.

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John D. Hewes

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